MAY 1 7 2010

EXHIBIT #1a

K100953

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: May 3, 2010

Contact: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland
Tel: +41 79 216 0070
E-Mail: gerhard.frick@microlife.ch

2. Name of the Device:

Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DZ1

Regulation Number: 21 CFR 880.2910
Regulation Name: Thermometer, Electronic, Clinical.
Regulatory Class: II
Product Code: FLL

3. Predicate Device Information:

Microlife Digital Infrared Forehead Thermometer, Model FR1DM1, K#033820

Thermofocus Non-contact Infrared Forehead Thermometer, Model 01500, K#072108.

4. Device Description:

The Microlife Non-contact Infrared Forehead Thermometer, Model FR1DZ1 is an electronic thermometer using an infrared sensor (thermopile)

to detect body temperature from the forehead. Microlife FR1DZ1 specially enables you to take measurements and judge the readings according to your local habits. It can measure for three types of readings comparable to readings measured at such three conventional measuring sites as rectal, oral, and axillary with an ordinary pen-type thermometer.

This Infrared Forehead Thermometer enables very safe and reliable measurements and with its technology the thermometer offers a very high clinical accuracy and has been designed to provide a maximum of user-friendliness.

The Microlife Non-Contact Infrared Forehead Thermometer consists mainly of seven parts:

a) Thermopile Sensor
b) ASIC
c) E2PROM IC
d) Lens
e) LCD and Backlight
f) 3 Keys (Offset 2 keys: optional), 1 Buzzer
g) 2 batteries AAA (LR03)

5. Intended Use:

The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DZ1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

6. Comparison to Predicate Devices:

The Microlife Non-contact Infrared Forehead Thermometer, Model FR1DZ1 is substantially equivalent to Microlife Digital Infrared Forehead Thermometer, Model FR1DM1, K#033820, and Thermofocus Non-contact Infrared Forehead Thermometer, Model 01500, K#072108, which has the same intended use and is similar in design to the predicate devices.

The Microlife Non-contact Infrared Forehead Thermometer FR1DZ1 and the predicate devices are identical in the temperature measurements algorithm and fundamental scientific technology, Microlife FR1DZ1 and FR1DM1 mainly differ by "non-contact", reference site, power supply, memory sets, backlight, lens etc., Microlife FR1DZ1 and Thermofocus 01500 mainly differ by the measuring range, power supply, memory sets, backlight, etc.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E1965, as well as IEC60601-1and IEC60601-1-2 requirements.

Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers.

8. Discussion of Clinical Tests Performed:

Controlled human clinical studies were conducted in accordance with ASTM E1965 using the Microlife Non-Contact Infrared Forehead Thermometer Model FR1DZ1. Clinical data was presented evaluating clinical bias, clinical uncertainty and clinical repeatability per clinical validation for Microlife FR1DZ1.

9. Conclusions:

The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DZ1 has the same intended use and similar technological characteristics as the Microlife Digital Infrared Forehead Thermometer Model FR1DM1 and Thermofocus Non-Contact Infrared Forehead Thermometer Model 01500. Moreover, bench testing contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Non-Contact Infrared Forehead Thermometer FR1DZ1 is substantially equivalent to the predicate devices FR1DM1 and Thermofocus 01500.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Microlife Intellectual Property GmbH
C/O Ms. Susan D. Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

MAY 17 2010

Re: K100953
Trade/Device Name: Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DZ1
Regulation Number: 21 CFR 880.2910
Regulation Name: Thermometer, Electronic, Clinical
Regulatory Class: II
Product Code: FLL
Dated: April 1, 2010
Received: April 6, 2010

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT B

Indications for Use

510(k) Number (if known): _____

Device Name: Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DZ1

Indications For Use:

The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DZ1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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